CASE AUTH/3860/12/23

COMPLAINANT v NOVARTIS PHARMACEUTICALS

Allegations about a Pluvicto promotional email

CASE SUMMARY

This case was in relation to a promotional email for Pluvicto sent by a third-party medical publisher to a health professional on behalf of Novartis.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 5.5	**Failing to be sufficiently clear as to the company's role and involvement**
Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 6.2	**Making an unsubstantiated claim**
Breach of Clause 11.2	**Promoting a medicine for an unlicensed indication**
Breach of Clause 12.1	**Failing to include UK prescribing information**
Breach of Clause 12.3	**Failing to include the non-proprietary name of the medicine immediately adjacent to the most prominent display of the brand name**
Breach of Clause 12.10	**Failing to include a black triangle adjacent to the first mention of the product in digital material**
Breach of Clause 15.6	**Disguising promotional material**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about Novartis.

COMPLAINT

The complaint wording is reproduced below:

> "I received an email from [third-party medical publisher] in my inbox yesterday afternoon that is of such low standards that it is nearly impossible to believe this was paid for by the 8th largest pharmaceutical company in the world. I am registered as a London based doctor with an interest in oncology on [third-party medical publisher]. I assume this is the reason I received this email.
> Having seen a few promotional leaflets and media in my career, this email is of shameful quality and poor standards
>
> 1. There is no suggestion in the email address or subject line that this is a promotional email. I thought the email would be educational and its only after I opened it that I realised its an advertisement disguised as education.
> 2. Only at the very end of the email is it made clear that this was paid for by Novartis.
> 3. There is no black triangle after Pluvicto until the last mention of the brand name in the email. I scrolled past 15 mentions of the brand name before the tiniest logo at the very end has a black triangle
> 4. There is no active ingredient listed after the first mention of Pluvicto either the indication mentioned is incorrect. The MHRA [Medicines and Healthcare products Regulatory Agency] granted a different indication that the EMA [European Medicines Agency] one.
> 5. This treatment is not novel. First clinical use was in 2014
> 6. There is no UK prescribing information attached to this email. The link opens the EMA SPC which does not state the UK price of £20,000.00 [link provided]"

When writing to Novartis, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 5.5, 6.1, 6.2, 11.2, 12.1, 12.3, 12.10 and 15.6 of the Code.

NOVARTIS' RESPONSE

The response from Novartis is reproduced below:

> "The Complaint relates to a promotional email sent to certain healthcare professionals through the [third-party] platform on behalf of Novartis Global (defined below) and relating to Novartis' product Pluvicto (lutetium-177 vipivotide tetraxetan). The activities which are the subject of the Complaint were conducted by Novartis' global affiliated company, Advanced Accelerator Applications International S.A (hereinafter referred to as '**Novartis Global**'). Notwithstanding the fact that Novartis Pharmaceuticals UK Limited ('**Novartis UK**') had no knowledge or oversight of the specific material in question, Novartis UK acknowledge that it is a well-established principle under the Code that UK companies are responsible for the acts or omissions of overseas parents or affiliates that come within the scope of the Code.
>
> The PMCPA has requested that Novartis UK consider whether certain clauses of the ABPI Code of Practice for the Pharmaceutical Industry 2021 (the '**Code**') have been breached.

The Complaint causes us great concern, as Novartis UK is committed to operating in accordance with the required standards, and we have taken its contents very seriously. We have set out our response in full below.

1. Novartis' relationship with [third-party]

The complainant refers to a healthcare professional facing website, owned by an organisation called [third-party medical publisher]. [Third-party medical publisher], owned by [third party's parent company], describes itself as the leading online global destination for physicians and healthcare professionals worldwide, offering the latest medical news and expert perspectives; essential point-of-care drug and disease information; and relevant professional education and CME [link provided]. [Third-party medical publisher] is highly regarded within the industry and by healthcare professionals as a provider of medical education. This includes both [third-party medical publisher] independent, editorial content and content which has been commissioned by the pharmaceutical industry.

Novartis Global and [third party's parent company] have a long-standing business relationship, working together on an extensive number of both promotional and non-promotional campaigns that include or exclude a UK HCP audience depending on the nature of the campaign. The vast majority of services are delivered without issues.

The specific material which is the subject of the Complaint concerns a promotional email sent by [third party's parent company] on 8 December 2023 through the [third-party medical publisher] platform, on behalf of Novartis Global (the '**Email**'). [Third party's parent company] was engaged through a fee for service arrangement with Novartis Global and the Email contains promotional information relating to Novartis' product Pluvicto, focussing on its mechanism of action.

Novartis Pharma AG has entered into a Master Services Agreement with [third party's parent company]. The services concerned by this Complaint were delivered under a Statement of Work between Novartis Global and [third party's parent company]. For completeness, a copy of the Statement of Work has been provided. Part 1, Section A (Description of Services), clause 3 of the Statement of Work permits [third party's parent company] to send a follow-up email to members of the target audience using material which has been supplied and approved by Novartis Global prior to deployment. The Email, which was received by the complainant, is the 'Recontact Email', as defined in the Statement of Work.

Novartis UK and Novartis Global understand that the Email should not have been received by HCPs in the UK. An explanation of the procedures to prevent this happening and an explanation of why HCPs in the UK received the Email is set out in the sections below.

Following receipt of the Complaint, Novartis Global promptly instructed [third party's parent company] to cease the distribution of the Email. Novartis UK understands from [third party's parent company] that the Email was opened by 44 unique recipients within the UK.

[Third party's parent company] offered Novartis UK and Novartis Global the opportunity to send a follow-up email to the UK HCPs that received the Email, apologising for the error

and explaining that this was not intended for a UK audience. Novartis UK thoroughly considered this option but felt that this would redraw attention to the Email given that time had passed. Please note that this was a finely balanced decision. If the PMCPA would prefer Novartis to take this action, Novartis UK will arrange with [third party's parent company] for such an email to be sent.

2. Global-led campaigns at Novartis

Novartis Global has clear policies in place governing the creation of promotional and non-promotional materials by Novartis Global associates. Section 2.1 of the '*AAA Global Materials Review and Approval Standard Operating Procedure'* (a copy of which is enclosed) clearly states the following requirements regarding local review and approval:

> *'In addition to global review and approval under this SOP as required, under no circumstances promotional or non-promotional materials may be externally used without prior local review and approval in each country where the material is intended to be used, in accordance with the applicable local governance.'*

Section 2.1 of the '*Promotional and Non-Promotional Materials Novartis Global P3 Guideline*' (a copy of which is provided) also clearly requires that promotional materials, which have been created at a Global level, must be reviewed at the local level prior to dissemination at that level. This same principle is also reflected on page 13 of the standard operating procedure titled '*Novartis Pharma Global Materials Clearance Committee (GMCC) Review and Approval*' (a copy of which is enclosed).

As a more general point, Novartis Global is aware that the requirements of the ABPI Code are more stringent than the regulatory requirements under the EFPIA Code and other European countries' local frameworks.

The local team have proactively created documents to ensure that when Global teams engage with UK healthcare professionals, the requirements of the ABPI Code are followed, such as the training slide deck *'Guideline to Engaging with or in the UK - 2021 ABPI'* (copies of which are provided). This guideline is proactively shared with global teams when they approach the UK to engage either in or with UK based healthcare professionals. The guideline was first created in July 2021 and has since been revised, with the latest version being created in August 2022.

The Novartis Global Medical Affairs team has previously issued guidance and delivered training on the specific topic of working with third party educational providers. [A] copy of a training slide deck created in August 2022 (updated in October 2022) [is provided]. Within this deck Slide 8 is dedicated to UK-specific considerations, demonstrating an understanding by the Global team that certain Global activities may not be permitted or appropriate in the UK. Of particular note, the training specifically states for medical education programs:

- not to target the UK (or any other country) audiences specifically if the 'global' content would not be acceptable there;
- the UK definition of 'promotion' is stricter than EFPIA;

- global associates need to have slides and content approved by the UK team if UK audiences are being targeted; and
- geo-blocking the UK is recommended where Novartis is responsible for the content and the content would be deemed inappropriate in the UK.

Novartis Global has also produced dedicated guidance on what should be considered when Novartis proposes to have its content hosted on the website of a third party. [A] copy of this guidance [is provided]. Slides 10 and 11 of this guidance make clear that the UK should be geo-blocked from content that has not been locally approved.

As part of self-regulation under the Code in the UK, Novartis UK has a robust and structured method for the review and approval of our materials and activities, which includes experienced signatories working collaboratively within brand teams to ensure compliance to our material certification SOP and ABPI Code of Practice. Had the Email or associated materials come under the rigorous view of the Novartis UK team, then they would have been challenged accordingly.

We have included some examples of how the interaction between Novartis UK and Novartis Global normally occurs in order to demonstrate how the process should work in practice (copy provided). In all of the matters referred to in [this document], following the interaction with the local team, Novartis Global confirmed that the UK would not be targeted by these highlighted campaigns.

However, as Novartis UK was not consulted on this occasion prior to the Email being distributed due to human error, it did not have the opportunity to review and provide direction to Novartis Global. Had the Novartis UK team been consulted:

(i) Novartis UK would have confirmed that the materials are not suitable for a UK audience; and
(ii) Novartis Global would have arranged for the UK to be geo-blocked, or specifically removed the UK from the list of countries to be geo-targeted by the campaign.

3. **Intended recipients of the Email**

In so far as the Email concerns Europe, the Email was intended to be distributed to healthcare professionals who:

(i) have registered through the [third party parent company]] network and in doing so consented to be contacted with promotional emails and content;
(ii) are practicing in the European Union ('**EU**'); and
(iii) specialise in oncology or nuclear medicine (or in the case of Germany, who specialise in urology).

That this was indeed Novartis Global's intention is evidenced on the face of the Email itself and can be evidenced by the following:

(i) the reference at the outset of the Email to Pluvicto being the '*first and only approved, in the **European Union**, PSMA-targeted radioligand therapy (RLT) for PSMA-positive mCRPC patients'*;
(ii) the inclusion of the **EU licensed indication**; and
(iii) the inclusion of the link to the **EU Summary of Product Characteristics** for Pluvicto.

However, rather than be disseminated to an audience of healthcare professionals practising in the EU, the email was instead sent to those practising in 'Europe'. This was an unfortunate human error by a Novartis Global associate.

Within Novartis 'Europe' is used to mean the 33 member countries of EFPIA as per clause 1.6 of the ABPI Code (therefore including the UK). [Third-party medical publisher] use the term 'Europe' similarly (specifically in this case, to include the UK).

Regrettably, a Novartis Global associate mistakenly used the term 'Europe' when instructing [third-party medical publisher] on the location of HCPs to target, rather than specifying only those HCPs working within the European Union. This can be seen in clause 5 of Part I, Section A of the Statement of Work. This error is the root cause of including healthcare professionals practising in the UK as recipients of the Email. Unfortunately, [third-party medical publisher] did not question this instruction.

This targeting error is the root cause of how this material came to the attention of the UK HCP who has made the current complaint.

As the material was not intended to target HCPs practising in the UK, the Novartis Global processes identified above to identify UK-facing material were not applied, and the requirement to consult with and gain prior approval from the Novartis UK team was not undertaken.

4. Novartis' responses to the alleged breaches

Novartis fully acknowledges and accepts that the mistake identified above should not have happened. However, the fact that it did has led directly to the unfortunate situation of an audience of UK healthcare professionals being in receipt of information that Novartis did not intend for them to see.

Any breaches of the ABPI Code that the PMCPA may find are a consequence of this disappointing human mistake. Novartis accepts full accountability for these occurring.

As requested by the PMCPA, we have borne in mind the requirements of Clauses 2, 5.1, 5.5, 6.1, 6.2, 11.2, 12.1, 12.3, 12.10 and 15.6 of the Code. We have set out some additional context below that we hope will be of use to the PMCPA when considering this Complaint.

<u>Clause 5.5</u>

The Email was never designed, nor intended to, reach a UK audience. While the Email does indicate the involvement of Novartis in line with EFPIA requirements, Novartis

accepts that its involvement should have been made clearer if this was intended to be placed in front of a UK HCP.

Clauses 6.1 and 6.2

The complainant states that Pluvicto '*is not novel'* and the '*first clinical use was in 2014'*. For completeness, Pluvicto received a PIM (Promising Innovative Medicine) designation on 24 August 2021, which was reflective of the unique mode of action in patients with prostate cancer. This was withdrawn on 4 April 2023 as a result of a UK marketing authorisation being granted. The UK marketing authorisation for Pluvicto was granted on 10 August 2022 and Pluvicto was first promoted to healthcare professionals in Great Britain on 25 October 2022.

From previous PMCPA case precedence (AUTH/3266/10/19 and AUTH/3279/11/19), Novartis recognises that an audience could understand 'novel' to mean new and unusual. At the date of the Complaint, 13.5 months had passed since the first promotion of the medicine in Great Britain. On this basis, a claim of 'novel' would cease to be applicable in the UK after 25 October 2023. Since that time, Novartis no longer makes such a claim in material intended for a UK audience and therefore acknowledges that its inclusion in the Email is inappropriate. Novartis accepts that the Email therefore constitutes a breach of clauses 6.1 and 6.2 for the use of the term 'novel'.

Clause 11.2, 12.1, 12.3 and 12.10

The material was designed and intended for an EU audience, meaning that:

(i) the indication for which Pluvicto is authorised in the EU was included. The promotion of Pluvicto was in accordance with the terms of the licensed indication in the EU. Although those terms are narrower than the UK, Novartis accepts that this is different to the indication for which Pluvicto is licensed in the UK;
(ii) a link to the EU Summary of Product Characteristics for Pluvicto was included;
(iii) there is no active ingredient listed after the first mention of Pluvicto. The active ingredient is stated at the end of the email, which meets the EFPIA requirements, but Novartis UK accepts that this is not sufficient for the UK; and
(iv) the black triangle is present but not located on the first mention of the name of the product. Novartis understands that the relevant UK standard has therefore not been met.

As explained above, the Email was never designed, nor intended to, reach a UK audience. As a consequence Novartis accepts that the Email does not meet the requirements of clause 11.2, 12.1, 12.3 or 12.10 of the ABPI Code.

Clause 15.6

The complainant asserts that '*there is no suggestion in the email address or subject line that this is a promotional email*' and that '*only after [they] opened it that [they] realised its an advertisement disguised as education*'.

Novartis acknowledges that the sender or subject line of the Email does not make clear the Email is promotional in nature. However, it was not Novartis Global's intention to disguise that the Email is a promotional communication.

In order to have received the Email, the relevant HCP could reasonably be expected to have consented to receive promotional materials from [third-party medical publisher] /[third party's parent company].

The Email was reviewed and approved by Novartis Global as a promotional asset under the EFPIA Code. A copy of the Novartis Global record of approving the Email under the EFPIA Code has been provided.

The reference to Pluvicto is prominent in the body of the Email, including the subject line and the Email does not imply that the contents are non-promotional, for example, that the contents provide information relating to safety.

[Third-party medical publisher] have included disclaimers at the end of the Email, stating unambiguously that the '*information contained in this email is brought to you by a third party sponsor'* and this '*promotional communication is provided by* [*third party's parent company*]*….who does not endorse and is not responsible for the accuracy of the content'*.
[Third-party medical publisher] does not allow any content that has received input from a pharmaceutical company to be published on its site without an adequate disclaimer.
[Third-party medical publisher]'s position is that to do so would be misleading for [third-party medical publisher]'s audience and create a sub optimal user experience, both of which could impact on [third-party medical publisher]'s reputation.
Finally, as mentioned above in relation to Clause 5.5, Novartis branding and address is included within the materials.

For the reasons set out above, Novartis refutes a breach of clause 15.6.

<u>Clause 5.1</u>

As the Email was inadvertently disseminated to a UK audience the appropriate process was not followed and therefore it did not undergo review by Novartis UK for compliance with the Code. Novartis UK accepts the consequences that flow from that mistake including that high standards were not maintained in this instance.

<u>Clause 2</u>

Novartis fully appreciates the seriousness of the Complaint. The relevant material was never intended for an audience of UK healthcare professionals. Novartis fully accepts any breaches of the Code that the PMCPA adjudicate to have taken place, where these are the consequence of the Email reaching a UK HCP. However, Novartis does not believe that a human error of the type made in this matter should result in a breach of Clause 2 of the Code being established in these specific circumstances.

As identified in section 3.2 above, Novartis has a robust compliance framework, with clear policies in place governing the creation of promotional and non-promotional materials by Novartis Global associates. Novartis has recently implemented a new Global policy 'Doing

Business Ethically' (effective as of 1 November 2023, [copy provided]). The policy underpins the way in which we do business at Novartis and aims to ensure that we maintain high ethical standards in all our external interactions. Novartis is very disappointed that a targeting mistake and failure of an individual associate to follow our policies has led to this Complaint. Lessons have been learnt by the Global team leading on this project and this will be followed up with additional training for the individuals involved on the relevant Novartis policies and processes.

Although the material did not contain the relevant prescribing information or licence for a UK audience (due to the fact that this was never intended for a UK audience), the licensed indication for Pluvicto in the EU is in fact narrower than the licensed indication in the UK with more stringent dose modification recommendations and more safety monitoring criteria. Patient safety was therefore not compromised by inadvertently referring to the EU SMPC rather than the GB SMPC.

It is also of note that Pluvicto can only be prescribed by a UK HCP with experience in prescribing nuclear medicines. Further, a full multi-disciplinary consultation is required before a prescribing decision will be taken. There are a small number of such specialist HCPs in the UK that can prescribe Pluvicto and Novartis believes it is reasonable to assume that these specialists would be aware of the licensed indication for Pluvicto in the UK. Although the black triangle does not meet the ABPI Code requirements, the black triangle was present in the material.

For these reasons, Novartis does not believe that patient safety was impacted as a result of this targeting error.

As a sophisticated pharmaceutical company operating all over the world, Novartis understands the intricacies of the varying regulatory frameworks across jurisdictions and the importance of appropriately localising materials and campaigns created at an above country level. Novartis is constantly adapting to ensure that its processes are fully aligned to the regulatory requirements and goes to great efforts to ensure that Novartis Global associates are aware of the varying intricacies of the local regulatory frameworks within which Novartis operates.

Key senior stakeholders (including the [job titles provided]) have been involved in investigating the circumstances that have given rise to this complaint, gathering the requested information, coordinating the response to this Complaint and considering what steps can reasonably and proportionately be taken to minimise the likelihood of such a situation arising again. These key senior stakeholders have asked for it to be made known that they are incredibly concerned that this situation has come to light. Additionally, Novartis UK is very disappointed that this situation has occurred due to circumstances outside of its control. As a company, Novartis seizes opportunities to re-educate associates on the key compliance frameworks within which the company operates and proactively disseminates learnings from mistakes, such as the one concerned by this Complaint, in order to minimise any risk of recurrence. Novartis UK commits to continue its efforts in the ongoing reinforcement of the Code and to re-educate associates working on globally-led campaigns on the Code requirements.

The complaint that has led to this case has arisen because of human error. Even with a robust compliance framework in place, human errors will inevitably occur, and Novartis hopes that the PMCPA understands this. Novartis does not believe that this human error has brought discredit upon, or reduced confidence in, the pharmaceutical industry.

With regards to the queries raised in your letter dated 13 December 2023:

(i) **A colour copy of the material at issue**: this is attached (colour copy of the Email copy provided);

(ii) **Details as to how the material was used and to whom it was distributed**: please see section 3 of our response;

(iii) **Copies of the certificate(s) approving the materials in question**: as explained in this letter of response, the Email was not intended for a UK audience and has therefore not been approved locally. The Email was reviewed and approved by Novartis Global as a promotional asset. A copy of the Novartis Global record of approving the Email under the EFPIA Code has been provided and

(iv) **Pluvicto (lutetium (177Lu) vipivotide tetraxetan) Great Britain SPC (Summary of Product Characteristics**: please see Great Britan SPC attached (copy provided).

5. Conclusion

Novartis UK and Novartis Global take their responsibilities under the Code extremely seriously. Significant resources are invested to ensure its associates develop a deep understanding of the requirements of the Code, that local and global policies are in accordance with the Code and that these contain appropriate checks to ensure that where mistakes happen, these are likely to be caught prior to material being available outside Novartis. The Email was never intended for a UK healthcare professional audience and should not have been disseminated as it was. Novartis accept the Code breaches found by the PMCPA as a consequence of the Email reaching a UK audience, due to the targeting error.

Human error and the isolated actions of one single employee who has failed to follow our policies and provide appropriate targeting instructions does not, and should not, reflect the diligent efforts that Novartis and its associates make to ensure that the conduct of the company accords with the highest standards and therefore complies with the requirements of the Code."

PANEL RULING

The Panel noted that the complaint concerned the acceptability of a promotional email sent by a medical publishing company to a UK health professional about Pluvicto, a prostate cancer treatment, on behalf of Novartis Global.

The Panel further noted that the PMCPA was dealing with a series of cases that involved the third-party medical publisher in question and various companies. The allegations and evidence provided in each case differed and thus consequentially the rulings. Each case was considered independently on the evidence before each Panel.

The Panel noted that, as accepted by Novartis UK, it was an established principle that a UK company was responsible for the acts and omissions of its overseas affiliates that came within the scope of the Code and that this principle applied irrespective of whether the UK company was aware of the act or omission in question. In this regard, the Panel noted that Novartis UK was not consulted by Novartis Global about the email.

The Panel noted Novartis' explanation for the error; that within Novartis 'Europe' is defined as the thirty-three member countries of EFPIA as per Clause 1.6 of the ABPI Code (therefore including the UK) and that the third-party medical publishing company used the term 'Europe' similarly (specifically in this case, to include the UK). A Novartis Global associate mistakenly used the term 'Europe' when instructing the third-party medical publishing company on the location of health professionals to target, rather than specifying only those health professionals working within the European Union. The email therefore did not undergo review by Novartis UK for compliance with the ABPI Code.

The Panel noted the differences between the UK and EU licensed indication. In the UK, Pluvicto was licensed for the treatment of adult patients with prostate specific membrane antigen (PSMA)-positive -metastatic castration-resistant prostate cancer who have been treated with androgen receptor (AR) pathway inhibition and taxane based chemotherapy or who are not medically suitable for taxanes. The Panel noted that the EU Pluvicto licence was similar but only for combination treatment with androgen deprivation therapy, and when the cancer was progressive.

The Panel noted that the copy of the material at issue provided by the complainant and by Novartis differed in that the complainant's version contained the word 'pluvicto' in lower case at the beginning of the email whereas Novartis' version was in capital letters. Novartis had not commented on this difference as part of its response. In addition, the complainant's version included the email fields for the addresses of the sender and recipient, date sent, and subject line. It also included the standard [third party's parent company]/third-party publisher's email footer with, among other things, options to unsubscribe and statements that the information was from a third-party sponsor and was promotional. The Panel made its ruling based on the version provided by the complainant.

The Panel examined the email noting that the sender of the email in question was the third-party medical publishing platform. The subject line read 'PLUVICTO :PSMA [prostate-specific membrane antigen]-targeted radioligand therapy for your mCRPC [metastatic castration resistant prostate cancer] patients'. The continuously scrolling email featured text within an outlined rectangular box at the top of which in a red band was 'pluvicto. The FIRST and ONLY

approved, in the European Union, PSMA-targeted radioligand therapy (RLT) for PSMA- positive mCRPC patients.' Text beneath described the patient population for whom Pluvicto was suitable describing it as a 'novel approach to treating your mCRPC-eligible patients' above a section which described Pluvicto's mechanism of action and included a video link. Further sections included 'EU indication' and references to PSMA status, concluding at the bottom of the scrolling webpage with a blue band which included amongst other things an apparent link to the summary of product characteristics (SPC), additional monitoring statement and indication.

Disguised promotion

The Panel noted the complainant's allegation that there was no suggestion in the email address or subject line that it was a promotional email. The complainant considered that the email would be educational and only realised it was promotional upon opening it. Novartis acknowledged that neither the sender nor subject line of the email made its promotional nature clear however, it was not Novartis Global's intention to disguise the email as a promotional communication. Novartis further noted that in order to have received the email, the relevant health professional could reasonably be expected to have consented to receive promotional materials from [third-party publisher].

The Panel noted that the allegation appeared to be limited to the initial impression given by the subject line and sender email address. The Panel noted that the sender of the email in question was the third-party medical publishing platform, the email address referred to the third-party medical publisher and professional resources follow up. The subject line read 'Pluvicto:PSMA [prostate-specific membrane antigen]-targeted radioligand therapy for your mCRPC [metastatic castration resistant prostate cancer] patients'. The Panel noted that the email subject line was the first, and might be the only, information read by the recipient and therefore the Panel considered that it was an important part of the material. The Panel was concerned that there was no indication that the email contained promotional material from a pharmaceutical company, either as part of the sender's email address or subject line and that the complainant had to open the email to be aware of its promotional nature.

The Panel understood that a range of emails might be sent by the medical publishing company and the fact that the recipient might have agreed to receive promotional emails from pharmaceutical companies did not in itself determine that all emails from the third-party medical publisher would be promotional or from a pharmaceutical company. Further, in the Panel's view, the disclaimers by the third-party medical publisher at the end of the continuously scrolling email, were insufficient in both content and location to correct the failure to make clear the material's promotional nature at the outset. The Panel considered that in their response, Novartis appeared to expect the recipient to know that the content was promotional.

The Panel considered that the initial impression given by the sender's email address and email subject line was such that, some readers might have assumed that it was clinical resource material about Pluvicto from the third-party medical publisher as implied by the email address and this meant that the promotional nature of the email was disguised, and the Panel ruled a **breach of Clause 15.6**.

Declaration of involvement

In relation to the allegation that Novartis' involvement was only clear at the very end of the email, the Panel noted that the first indirect indication of any Novartis involvement appeared

towards the end of the long continuously scrolling email in the blue band described above and in a very small typeface, '© 2023 Novartis Pharma AG' beneath the larger but still small corporate name and logo. Beneath the promotional body of the continuously scrolling email was, amongst other things, an opt out for 'sponsored email communications' and in even smaller typeface a statement that the email was 'brought to you by a third-party sponsor' and that the 'promotional communication' was provided by the named third party medical publishing company. The Panel noted its comments above about the disclaimers of the medical publishing company.

The Panel noted that Clause 5.5 required amongst other things material relating to medicines and their uses to clearly indicate the role of the pharmaceutical company and the relevant supplementary information provided that the declaration must be sufficiently prominent to ensure that readers are aware of it at the outset.

The Panel noted that the continuously scrolling email did not contain a clear or prominent statement of Novartis' involvement at the outset and as acknowledged by Novartis failed to meet the requirements of **Clause 5.5 and a breach was ruled** accordingly.

Inverted black triangle

In relation to the allegation that the black triangle did not appear until the last mention of the brand name, the Panel noted Novartis' submission that the black triangle was present but not located at the first mention of the name of the product. The Panel noted that the inverted black triangle appeared at the very bottom of the promotional part of the version of the continuously scrolling email provided by the complainant adjacent to the brand name in the bottom right hand corner of the bottom blue band described above, where it would only be seen by those who opened the email and scrolled down to the end. It also appeared as a standalone symbol next to the additional monitoring statement within the same section.

The Panel noted that Clause 12.10 provided that the inverted black triangle must appear in digital communications adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product. In the Panel's view, the inverted black triangle was a well-known and established symbol for health professionals. Its appropriate use was an important part of medicines regulation and contributed towards patient safety. The Panel considered as acknowledged by Novartis that the email did not meet the requirements of the Code in relation to the inverted black triangle. The Panel ruled a **breach of Clause 12.10** of the Code.

List of active ingredients

In relation to the allegation that there was no active ingredient listed after the first mention of Pluvicto, the Panel noted that the subject line of the email was the first appearance of the brand name for the promotional material in question; it might be the only part of the material read by recipients. The Panel considered that the non-proprietary name or list of active ingredients was not present immediately adjacent to the brand name at its first appearance, rather it appeared at

the third mention of the brand name which was within the body of the email in question. A **breach of Clause 12.3** was ruled as acknowledged by Novartis.

Omission of UK licensed indication

In relation to the allegation that the licensed indication was incorrect, the Panel noted that the indication for which Pluvicto was authorised in the EU was included rather than the UK licence and further noted Novartis' submission that the promotion of Pluvicto was in accordance with the terms of its licensed indication in the EU and that although those terms were narrower than the UK, Novartis accepted that the requirements of Clause 11.2 had not been met. The Panel noted the differences between the UK and European licences set out above and did not necessarily agree with Novartis' submission about the impact of these differences. The material did not refer to or reflect the UK licence and thus promotion of Pluvicto was inconsistent with the particulars listed in its UK SPC and the Panel ruled a **breach of Clause 11.2** accordingly.

Use of the term 'novel'

In relation to the allegation that the treatment was not novel and the reference to the first clinical use being in 2014, the Panel noted that the email stated that Pluvicto 'is a PSMA-targeted radioligand therapy (RLT) that may offer you a novel approach' to treating eligible patients. The Panel noted that the complainant appeared to be indirectly referring to the Code requirement that the word 'new' must not be used to describe amongst other things, any treatment which has been generally available for more than twelve months. The Panel considered that contrary to the complainant's inference, 'novel' was potentially broader than the word 'new'. The Panel noted Novartis' reference to Case AUTH/3266/10/19 where, within the context of a press release, the Panel had considered the word 'novel' meant that a product, with orphan status, was new and unusual. The Panel considered that the meaning of the word 'novel' should be decided on a case-by-case basis bearing in mind its context including the nature of the material and the audience.

The Panel noted that the prominent red band at the very beginning of the email, above the section of the email which contained the word 'novel', was headed 'pluvicto', and bore the phrase 'FIRST' and ONLY approved…', and considered that this might be seen by some readers as an implication that the product was new. However, the Panel noted that the term in question, 'novel' appeared in a sentence which described Pluvicto as 'a PSMA-targeted radioligand (RLT) that may offer you a novel approach to treating your mCRPC eligible patients'. Within this context the Panel accepted that some readers might consider that the word 'novel' when considered in isolation was describing a different treatment approach or mechanism of action which was outlined in detail in the subsequent section. However, the Panel considered the prominent headline claim 'FIRST and ONLY…' could imply to some readers and particularly to a busy health professional glancing at the material that the product was new and further that the proximity of the subsequent claim including the word 'novel' could add to this impression. On balance, in the Panel's view, the combination of the use of the word 'novel' and the prominent phrase 'FIRST and ONLY' in the email created an ambiguous impression that the product was new as alleged and that was not so. The Panel therefore considered that 'novel' in this context was ambiguous contrary to the requirements of Clause 6.1, and a **breach of Clause 6.1** was

ruled. The Panel considered that the ambiguous implication was incapable of substantiation**;** a **breach of Clause 6.2** was ruled.

Omission of UK prescribing information

In relation to the allegation that there was no UK prescribing information and that the link opened the EMA SPC which did not state the UK price of £20,000, the Panel noted Novartis' submission that a link to the EU Summary of Product Characteristics for Pluvicto was included and that the email was not designed for a UK audience. The Panel noted the cost of the medicine was not provided as required by Clause 12.2 which set out the content of prescribing information and further there were differences between the UK and EU SPC. The Panel ruled a **breach of Clause 12.1** of the Code which required the information in Clause 12.2 to be provided.

Clauses 5.1 and 2

The Panel noted Novartis' submission that the email was inadvertently disseminated to a UK audience and that the appropriate process was not followed which therefore meant that the email did not undergo review by Novartis UK for compliance with the ABPI Code.

The Panel noted Novartis' reference to the matter arising as a result of human error and the isolated actions of one single employee who had failed to follow its policies and provide appropriate targeting instructions. The Panel considered that the risk of the email reaching a UK audience was entirely foreseeable given both Novartis and the third-party medical publishing company defined Europe as those countries that were members of EFPIA which was broader than political membership of the European Union. The Panel noted further that there were differences between both memberships and the number of countries located geographically in Europe. The email in question was intended for health professionals practising within the European Union.

The Panel accepted that Novartis Global's compliance documents to a certain extent covered the scenario at issue; both the 'AAA Global Materials Review and Approval Standard Operating Procedure and the Promotional and Non-Promotional Materials Novartis Global P3 Guideline' required local approval and further noted Novartis' submission about its related Global training activities. Nonetheless, the Panel queried whether the need to geo-block should have arisen given the material was intended for health professionals based within the European Union. In the Panel's view, the guidance materials about global approval and distribution of materials should have been particularly clear about the company definition of Europe and the difference between that definition and membership of the European Union and location geographically in Europe so that the risk was appropriately identified and managed, and employees should have been trained accordingly. The apparent absence of such clear guidance and training increased the risk that a European target audience might not be appropriately identified. In this regard the

Panel noted that it had not been provided with the meta data identifying the intended audience when the email was approved.

Noting its rulings and comments above in relation to the failure to ensure local approval, and as acknowledged by Novartis, the Panel considered that high standards had not been maintained. A **breach of Clause 5.1** was ruled.

In relation to the complainant's allegation that the material was of shameful quality and poor standards the Panel also considered Clause 2, noting the narrow nature of the allegations. The complainant did not refer to patient safety concerns but did refer to poor standards. The Panel noted Novartis' submission that patient safety was not compromised by referring to the EU rather than the UK SPC as although the material did not contain the relevant prescribing information or indication for a UK audience (due to the fact that this was never intended for a UK audience), the licensed indication for Pluvicto in the EU was narrower than in the UK with more stringent dose modification recommendations and more safety monitoring criteria.

Whilst the Panel had certain concerns about the differences between the UK and EU SPCs overall the Panel did not consider that the complaint went beyond noting, in a very narrow sense, that the material was based on the EU SPC.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel considered, on balance, that the ruling of a breach of Clause 5.1 adequately covered the complainant's concerns and given the narrow complaint the circumstances of this case did not merit a ruling of a breach of **Clause 2. No breach** was ruled in this regard.

Complaint received **9 December 2023**

Case completed **23 April 2025**